

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 15-085V

MYKELLE JIVON D'TIOLE,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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Special Master Corcoran

Filed: December 21, 2016

Decision Without
Hearing; Dismissal; Influenza
("Flu") Vaccine; Narcolepsy;
Cataplexy; Motion for
Reconsideration.

Curtis R. Webb, Curtis R. Webb, Twin Falls, ID, for Petitioner.

Lara Ann Englund, U.S. Dep't of Justice, Washington, DC, for Respondent.

ORDER DENYING MOTION FOR RECONSIDERATION¹

On January 27, 2015, Mykelle Jivon D'Tiole's parents filed a petition² seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine

¹ Because this Order contains a reasoned explanation for my actions in this case, it will be posted on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Order will be available to the public. *Id.*

² The matter was originally filed by Petitioner's parents on his behalf, due to his minor status. After Mr. D'Tiole attained majority while the case was pending, I ordered that he be identified as the petitioner in the caption. ECF No. 27.

Program”).³ In it, Petitioner alleged that the influenza (“flu”) vaccine he received on December 13, 2011 (the “FluMist” form), caused him to develop narcolepsy with cataplexy.

After the parties filed expert reports, and based upon my initial review of the case record, I proposed that the matter be decided without holding an evidentiary hearing and invited briefing on the substantive merits of Petitioner’s claim. I reviewed the parties’ submissions and then, in a decision dated November 28, 2016, denied entitlement, finding that Petitioner had not carried his burden of proof overall. *See* Decision, dated November 28, 2016 (ECF No. 39) (the “Entitlement Decision”).

Petitioner has now filed a timely motion requesting reconsideration of my denial of entitlement. *See* Motion for Reconsideration, dated December 19, 2016 (“Motion”). For the reasons stated below, the motion is **DENIED**.

Analysis

Vaccine Rule 10(e) governs motions for reconsideration of a special master’s decision, and provides that “[e]ither party may file a motion for reconsideration of the special master’s decision within 21 days after the issuance of the decision” Vaccine Rule 10(e)(1). Special masters have the discretion to grant a motion for reconsideration if to do so would be in the “interest of justice.” Vaccine Rule 10(e)(3).

As noted by another special master, “there is a dearth of law interpreting Vaccine Rule 10(e)(3),” beyond the conclusion that (as the rule itself makes clear) it is within the special master’s discretion to decide what the “interest of justice” is in a given case. *R.K. v. Sec’y of Health & Human Servs.*, No. 03-632V, 2010 WL 5572074, at *3 (Fed. Cl. Spec. Mstr. Jan. 10, 2011) (granting reconsideration of decision dismissing case for failure to prosecute). Many decisions analogize the standard for reconsideration to the “manifest injustice” standard utilized under Rule 59(a) of the Rules of the Court of Federal Claims,⁴ which has been defined to be unfairness that is “clearly apparent or obvious.” *Amnex, Inc. v. United States*, 52 Fed. Cl. 555, 557 (2002); *see also R.K.*, 2010 WL 5572074, at *3-5 (citations omitted). Overall, however, the “interest of justice” standard is somewhat more lenient, emphasizing whether reconsideration would provide a Vaccine Act petitioner a full opportunity to prove her case. *Id.* at *5.

³ The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter “Vaccine Act” or “the Act”]. Individual section references hereafter will be to § 300aa of the Act.

⁴ The Court of Federal Claims has interpreted Rules of the United States Court of Federal Claims (“RCFC”) 59(a) as setting forth three possible bases for obtaining reconsideration of an order: (a) a change in controlling law; (b) the presence of previously unavailable evidence; or (c) manifest injustice. *System Fuels, Inc. v. United States*, 79 Fed. Cl. 182, 184 (2007).

Prior to evaluation of Petitioner's argument for reconsideration, a brief recitation of the basis for my Entitlement Decision is required. Petitioner's claim was based on the contention that his December 2011 receipt of FluMist – a live attenuated influenza vaccine ("LAIV") containing the H1N1 strain of the flu virus – could, and did, cause his narcolepsy, which began no sooner than two months after vaccination but which was only diagnosed much later in 2012. Entitlement Decision at 2. Petitioner and his expert, Dr. Lawrence Steinman, relied heavily on research involving a different form of the flu vaccine – an adjuvanted inactive pandemic influenza vaccine – and in particular a specific version, Pandemrix, that was not available in the United States but which has been credibly associated with a narcolepsy outbreak in Europe. *Id.* at 26. Dr. Steinman co-authored the two articles most relied-upon by Petitioner for the theory (referenced in the Entitlement Decision as "Ahmed I" and "Ahmed II"), making him an especially apt expert in this case. *Id.* at 27.

However, review of Petitioner's argument, plus the three expert reports submitted by Dr. Steinman, revealed weaknesses in applying Dr. Steinman's research to this case. The Ahmed I and II articles did yeoman's work advancing the understanding of narcolepsy as an autoimmune condition in which nucleoprotein antibodies generated from a cross-reaction between the H1N1 strains of Pandemrix and like-manufactured flu vaccines interfered with hypocretin receptors in the brain, causing narcolepsy with cataplexy – but they were specific to those forms and not to an LAIV like FluMist. Entitlement Decision at 27. Indeed – the research upon which those articles were based found that the manufacturing process by which the H1N1 strains in Pandemrix and like vaccines were rendered inactive led to an increase in the numbers of the nucleoproteins believed to be central to the proposed autoimmune mechanistic process. At the same time, however, Ahmed I and II specifically noted that (a) an LAIV was *less* likely to cause the same autoimmune reaction, and (b) even some vaccines more similar in make-up to Pandemrix than FluMist (such as Focetria) were unlikely to cause that cross-reaction because they were manufactured in a way that diminished the amounts of nucleoproteins present in the vaccine. *Id.* at 27-28.

Aware of these problems in his theory, Petitioner (via Dr. Steinman) attempted to argue that the H1N1 wild virus was itself associated with narcolepsy (thus allowing for the conclusion that *any* vaccine containing the strain had the same capacity to cause narcolepsy). But besides finding that this assertion was contrary to Ahmed I and II (since they studied a number of forms of vaccine, all containing the H1N1 strain, but specifically found that certain versions were less associated with increases in narcolepsy than Pandemrix), the Entitlement Decision also observed that there were several reliable large-scale epidemiologic studies standing in the way of Petitioner's argument. Entitlement Decision at 28-29. Even some of the science that had first observed a relationship between Pandemrix and narcolepsy (in particular, articles by Partinen

directly relating to the narcolepsy outbreak in Europe after administration of Pandemrix) had not similarly found a relationship with the wild virus. *Id.* at 28.

I provided the parties an opportunity to brief the claim based upon the filed record, after I concluded that the case turned not on the nature of Petitioner's illness but rather on the proposed causation theory. Entitlement Decision at 18-19. After weighing the evidence, reviewing the medical literature filed, and considering the parties' briefs, I concluded that Petitioner had not made a preponderant showing of an association between the wild virus and narcolepsy sufficient to link Ahmed I and II's findings to the FluMist form of vaccine at issue in this case. *Id.* at 32.

Petitioner's request for reconsideration primarily asserts that the Entitlement Decision "did not consider significant evidence" about the relationship between the wild H1N1 influenza virus and an increase in narcolepsy in Beijing, China, as observed in a piece of literature relied upon by Petitioner – F. Han et al., *Narcolepsy Onset is Seasonal and Increased Following the 2009 H1N1 Pandemic in China*, 70 Am. Neurological Ass'n 410 (2011). Motion at 1, 2-6; *see also* Pet'r's Ex. 36.⁵ But this is incorrect. The Entitlement Decision discussed Han and other relevant articles involving the relationship between the wild H1N1 virus and narcolepsy. In fact, the Entitlement Decision noted that Ahmed I and II *themselves* observed limits in Han's application to the argument for which it is now cited. *See* Entitlement Decision at 28, *citing* Ahmed II at 6 (observing that "studies outside China have not reported an increase in narcolepsy cases in unvaccinated subjects," and proposing that the high residential density of Beijing might simply have made the studied residents more susceptible to the flu generally).

The Entitlement Decision does not ignore Han or dispute its findings. Rather, the Entitlement Decision does not provide Han the weight Petitioner believes it should have received. Indeed, Respondent's experts submitted equally-valid literature that undermined Petitioner's argument about the wild virus's association with narcolepsy. *See, e.g.*, Entitlement Decision at 13, citing M. Partinen et al., *No Serological Evidence of Influenza A H1N1pdm09 Virus Infection as a Contributing Factor in Childhood Narcolepsy after Pandemrix Vaccination Campaign in Finland*, 8 PLOSone 1:7 (2013) (filed as Resp't's Ex. A-2).

Thus, Petitioner's argument amounts to a request that I reweigh the evidence and find in his favor, based on a more detailed recitation of arguments already made in his brief, as well as the three reports filed by Dr. Steinman (which also argued for a link between the wild virus and narcolepsy). This is not a persuasive basis for reconsideration, however, because (a) it raises no *new* arguments or evidence that could not have been argued before, and (b) the fact that a

⁵ In support of this part of his argument, Petitioner has filed ten additional pieces of scientific or medical literature. *See* Motion at 4-6; ECF No. 43 (filing Exhibits 75-84). Of these, however, only two are new. Three of the articles were already filed in the action, and an additional five were referenced in the Ahmed I and II articles that were discussed extensively in the Entitlement Decision. Thus, none of these items constitute literature that was not available to Petitioner or his expert prior to the Entitlement Decision – a fact Petitioner acknowledges. Motion at 4.

claimant disputes a special master's evaluation of evidence does not constitute "manifest injustice." I therefore decline the request for reconsideration on this basis.

Petitioner's other arguments for reconsideration are also unpersuasive. Petitioner bases his second grounds for reconsideration upon a single item of literature suggesting that narcolepsy centers in the United States, France, and Canada also observed an increase in the incidence of narcolepsy after the H1N1 pandemic, and even a single instance of association between an LAIV and narcolepsy, citing an exhibit filed by Respondent's expert, Dr. Kohrman, Y. Dauvilliers et al., *Letter to the Editor: Post H1N1 Narcolepsy-Cataplexy*, 33 SLEEP 11:1428-1430, filed as Resp't's Ex. A-4 ("Dauvilliers"). Motion at 7-9. Dr. Kohrman's First Expert Report (filed as Resp't's Ex. A) referenced Dauvilliers in the section of his report dealing with Han, but he dismissed its probative value because it was an observational report rather than true epidemiologic study, and therefore was not helpful in establishing a causal relationship between the H1N1 wild virus and narcolepsy. First Kohrman Report at 10-11.

Contrary to Petitioner's suggestion, in fact I reviewed Dauvilliers in making my decision (as with *all* items filed, a point specifically made in the Entitlement Decision (*see* Entitlement Decision at 25)). I did not, however, find it warranted a full discussion in the body of the Decision, for several reasons. First, it is, as Dr. Kohrman observed, a two-page letter to the editor, rather than an article dealing with a reliable, substantiated clinical or epidemiologic study with proper samples and controls. Second, it was cited by Respondent, but not by Petitioner, further minimizing its significance in comparison to similar articles, like Han, that Petitioner repeatedly emphasized.⁶ Dauvilliers itself acknowledges that its observations were limited due to the fact that most of the studied population had either been vaccinated or had incurred a wild H1N1 infection, creating difficulty in making a specific association between narcolepsy onset and H1N1 infection as opposed to vaccination. Dauvilliers at 1429.

I therefore focused my discussion in the Entitlement Decision on explaining why the link observed between the wild virus and narcolepsy, while intriguing, was insufficient evidence to relate FluMist similarly, rather than in consideration of a tangential piece of literature not deemed significant by Petitioner at the time I was to decide the merits of his claim. *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1347 (Fed. Cir. 2010) (not error for special master to disregard piece of scientific literature not raised as significant by petitioner). Dauvilliers thus provides no more basis for reconsideration than Han. Reconsideration should be reserved for situations where there is a compelling reason to evaluate an argument that could not

⁶ Petitioner did not reference or raise Dauvilliers in his brief opposing dismissal of the case, and Dr. Steinman's second and third expert reports (prepared and filed after Dr. Kohrman's first report) also make no mention of Dauvilliers.

have been made earlier, or was justifiably omitted – *not* because a claimant or his counsel regrets not amplifying an argument, or component of the record, after the chance to do so has passed.

Finally, Petitioner contends that I failed to consider the determinations of an epidemiologic study demonstrating an increased incidence of narcolepsy associated with another version of the inactivated H1N1 pandemic vaccine, Arepanrix, administered in Canada, as discussed in J. Montplaisir et al., *Risk of Narcolepsy Associated with Inactivated Adjuvanted (AS03) A/H1N1 (2009) Pandemic Influenza Vaccine in Quebec*, 9 PLOSone 9:1-9, filed as Pet'r's Ex. 81 on December 20, 2016 ("Montplaisir"). Motion at 2, 9-10. Montplaisir was not filed by Petitioner before the issuance of my Entitlement Decision, although (because it is referenced among the 80 articles cited as authorities in Ahmed II – which was analyzed extensively in the Entitlement Decision) it well could have been had Petitioner deemed it significant.⁷

Despite Petitioner's failure to file Montplaisir prior to my issuance of the Entitlement Decision, I have now reviewed it, but do not find that it provides grounds for reconsideration. My reasoning runs parallel to the authors of Ahmed II, who themselves found that not all forms of vaccines more akin to Pandemrix than FluMist were similarly associated with narcolepsy. *See* Entitlement Decision at 8. Arepanrix is an adjuvanted inactive A/H1N1 pandemic flu vaccine, similar to Pandemrix. Montplaisir at 2. Indeed, it was specifically included in the studies underlying Ahmed II, and its levels of nucleoproteins measured, with the finding that those levels were closer in sum to Pandemrix than Focetria – another inactivated flu vaccine that was not associated with narcolepsy despite the fact that it too contained nucleoproteins. Ahmed II at 8. Thus, the fact that a vaccine much like Pandemrix might be associated with narcolepsy does not mean that an LAIV such as FluMist would be as well – any more than if Petitioner argued (contrary to Dr. Steinman's own work in Ahmed II) that the similarities between Focetria and Pandemrix mean both are equally associated with narcolepsy – a proposition Ahmed II expressly disavows. Ahmed II at 1 ("[c]urrently, no increased risk [for narcolepsy] has been reported for the MF59-adjuvanted A(H1N1)pdm09 vaccine (Focetria)"). It does not stand as a newly-discovered, let alone critical, evidentiary basis for reconsideration.

⁷ The implications of this argument are particularly troubling. Vaccine Program petitioners routinely file pieces of medical or scientific literature in support of their claims that, in turn, contain lengthy authorities sections referencing *even more* items of scientific or medical literature that were relied upon in the creation of the primary piece of literature. After a full and fair opportunity to defend his claim (which included the ability to file as many items of literature as he felt necessary), Petitioner has now selected Montplaisir – an article he did not deem significant enough at the time to file as a separate exhibit – and highlights it as critical to his claim. In so doing, he suggests that a special master's failure to sift it out from the primary article's table of authorities (which in this case included 80 separate items) amounts to a potential decisional error warranting reconsideration. If this is correct, then the decisions of special masters should be evaluating *every* single item referenced on a filed piece of literature's bibliography or table of authorities, since any one of them could later be deemed important even if overlooked by a claimant before – a prospect that goes far beyond what special masters are actually called upon to do in assessing the evidence in the record in support of a vaccine injury claim.

The request for reconsideration based upon Dauvilliers and Montplaisir should also be placed in the context of the evidence filed in this case, and upon which the Entitlement Decision was based. At the time of the Entitlement Decision, Petitioner had filed a total of 55 separate pieces of scientific or medical literature. Consistent with the exercise of my duties, I reviewed all submitted articles, although I did not find all merited extensive discussion or mention in the Entitlement Decision – an exercise of my discretion that applicable law supports. Entitlement Decision at 25. Now, Petitioner references two items that were expressly not discussed, but argues (with respect to Montplaisir, for the first time) that their significance is so great that no correct decision could be arrived at without doing so. Although Petitioner may well have a good faith (if retrospective) belief in the significance of this proof, the care with which he has selected items not discussed in the Entitlement Decision (and largely not stressed by Petitioner in his prior briefs or expert reports either) seems more reflective of an attempt to sow seeds for future arguments on review than to identify appropriate grounds for reconsideration.

I therefore find (in exercising my discretion) that the interest of justice does not compel revision of my original decision. Accordingly, the Motion for Reconsideration is DENIED.

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master